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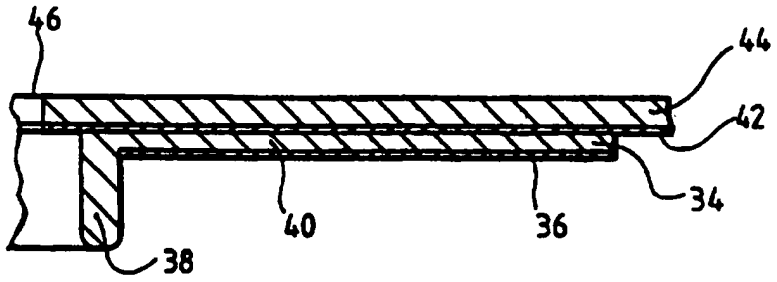
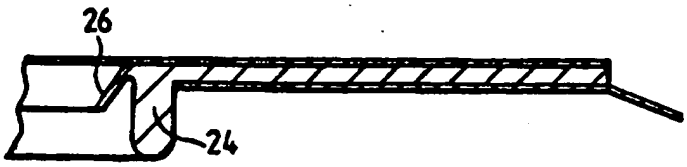
(54) Title: OSTOMY BAGS

(57) Abstract

The invention provides a coupling device for mounting an ostomy bag (2, 4) about a stomal opening in the body wall of the patient and to an ostomy bag (2, 4) fitted with the coupling device; the device comprising: (i) a first annular member (34) having on one side thereof a layer of a dermatologically compatible adhesive (44) for temporarily adhering the first annular member (34) to the patient's skin about the stomal opening, and on the other side therof having a first annular sealing element (38), and a first annular bonding region (36) surrounding the first annular sealing element (38); and (ii) a second annular member (18) for securing to an ostomy bag about the stomal waste-receiving opening thereof; the second annular member (18) having a second annular sealing element (24, 26) surrounded by a second annular bonding region (22); either the first annular bonding region (36), or the second annular bonding region (22), or both, having a layer of a repositionable adhesive thereon; the arrangement being such that when the first and second annular members (34, 18) are brought together the first and second annular sealing elements (38, 24, 26) co-operate to form a substantially water-tight seal, and the first and second annular bonding regions (18, 36) co-operate to form a releasable adhesive bond therebetween.





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OSTOMY BAGS

This invention relates to ostomy bags and more particularly to coupling devices for fastening ostomy bags to a patient's body.

The use of ostomy bags, such as ileostomy and colostomy bags, to collect bodily waste draining from a stomal opening in the patient's body wall, is well known. Ostomy bags can be secured to the patient by means of a belt or strap, but more usually they are affixed to the patient by means of an adhesive flange which surrounds the stomal orifice. Typically the adhesive flange has a layer of a dermatologically compatible hydrocolloid adhesive. Although the hydrocolloid adhesives are relatively benign, repeated application and removal of fresh adhesive flanges can cause irritation and discomfort to the patient and, for this reason, in situations where an ostomy bag needs to be changed frequently, a two-piece bag is used. Such two-piece bags typically consist of a two-part connector, one part of which has the adhesive flange attached thereto, and the other part of which is attached to the ostomy bag. With such an arrangement, the adhesive flange may be left in position on the patient's skin whilst the ostomy bag can be replaced as required.

A disadvantage with existing two-part connectors is that they are frequently formed from a relatively rigid material, and have a high profile which means that they can be seen through the patient's clothing. In addition, they

can be somewhat uncomfortable, as well as being relatively cumbersome to use. Some devices use a locking ring arrangement which requires accurate positioning and good manual dexterity. This can pose problems for people who have impaired manual dexterity.

At the present time, there remains a need for a two-piece ostomy bag in which the two-part connector is relatively flexible, has a low profile and cannot be seen through the patient's clothing, and which is comfortable to wear. It is an object of the present invention to provide such an arrangement.

Accordingly, in a first aspect, the invention provides a coupling device for mounting an ostomy bag about a stomal opening in the body wall of the patient; the device comprising:

(i) a first annular member having on one side thereof a layer of a dermatologically compatible adhesive for temporarily adhering the first annular member to the patient's skin about the stomal opening, and on the other side thereof having a first annular sealing element, and a first annular bonding region surrounding the first annular sealing element; and

(ii) a second annular member for securing to an ostomy bag about the stomal waste-receiving opening thereof; the second annular member having a second annular sealing element surrounded by a second annular bonding region;

either the first annular bonding region, or the second annular bonding region, or both, having a layer of a repositionable adhesive thereon; the arrangement being such that when the first and second annular members are brought together, the first and second annular sealing elements co-operate to form a substantially water-tight seal, and the first and second annular

bonding regions co-operate to form a releasable adhesive bond therebetween.

In another aspect, the invention provides an ostomy bag having a two-part coupling device for mounting the ostomy bag about a stomal opening on the body wall of a patient; the coupling device comprising:

(i) a first annular member having on one side thereof a layer of a dermatologically compatible adhesive for temporarily adhering the first annular member to the patient's skin about the stomal opening, and on the other side thereof having a first annular sealing element, and a first annular bonding region surrounding the first annular sealing element; and

(ii) a second annular member secured to the ostomy bag about the stomal waste-receiving opening thereof; the second annular member having a second annular sealing element surrounded by a second annular bonding region.

either the first annular bonding region, or the second annular bonding region, or both, having a layer of a repositionable adhesive thereon; the arrangement being such that when the first and second annular members are brought together, the first and second annular sealing elements co-operate to form a substantially water-tight seal, and the first and second annular bonding regions co-operate to form a releasable adhesive bond therebetween.

It is preferred that the first and second annular sealing elements are arranged concentrically so that the sealing is effected by radially confronting surfaces of the two sealing elements.

By arranging the sealing members concentrically, it is possible to reduce the height of the coupling device which

in turn means that it is not so visible through the patient's clothing.

One of the first and second annular sealing elements can be an upstanding annular rim, and the other can be provided with sealing means for sealing against the upstanding annular ring.

The sealing means preferably takes the form of a lip seal.

It is preferred that the upstanding annular rim constitutes the first annular sealing element whilst the sealing means (e.g. the lip seal) constitutes the second annular sealing element.

Where one of the annular sealing elements is in the form of an upstanding annular rim, then the other annular sealing element can take the form of an annular collar which fits about the upstanding annular rim. It is preferred that the depth of the annular collar is such that when the first and second annular members are brought together, the annular collar is substantially flush with the top of the upstanding annular rim.

It is preferred both that one of the annular bonding zones has a layer of a releasable adhesive thereon, the releasable adhesive preferably being in the form of an adhesive tape which engages a release tape on the other annular bonding region.

The first and second annular members are preferably formed of a flexible polymeric material, and examples of such material include ethylvinylacetate copolymer (EVA). It is preferred that both the first and second annular members are formed from the same polymeric material (e.g. EVA).

One or other of the first and second annular members can be provided with locating means for assisting correct positioning of one of the annular members with respect to the other. For example, the locating means can take the form of a guide wall or guide lugs attached to one of the annular members, which guide walls or guide lugs are disposed about the periphery of one of the annular members so as to guide the other annular member into a position at which the first and second sealing members can be engaged in sealing contact.

In its simplest form, the guiding lugs or guiding means can be defined by a pair of guide lugs at spaced apart locations on the outer periphery of one of the annular members, and preferably the first annular member. Alternatively, the guide means can take the form of an arcuate guide wall extending between two spaced apart points on the periphery of the annular member.

The invention will now be exemplified by reference to the particular embodiments shown in the accompanying drawings Figures 1 to 7; in which

Figure 1 is a view from one side of an ostomy bag according to one embodiment of the invention;

Figure 2 is an exploded view of the ostomy bag of Figure 1;

Figure 3 is a view from one side of an adhesive flange used in conjunction with the ostomy bag of Figures 1 and 2;

Figure 4 is an exploded view of the adhesive flange of Figure 3;

Figure 5 is a part sectional elevation through the adhesive flange shown in Figure 3;

Figure 6 is a part sectional elevation through an annular member secured to the stomal opening in the ostomy bag of Figure 1; and

Figure 7 is a part sectional view showing the adhesive flange and annular member of Figures 5 and 6 adhered together.

Referring now to the drawings, an ostomy bag according to one embodiment of the invention is formed from front 2 and rear 4 sheets of a tough waterproof multilaminar film material comprising a layer of polyvinylidene dichloride and optionally one or more further barrier layers sandwiched between two layers of ethylenevinylacetate (EVA). Such film can be obtained from W. R. Grace GmbH of Larderstedt, Germany. Sheets 2 and 4 are sealed together around their peripheral margins 6 and 8 by welding, for example RF welding. A third layer 10 which is a comfort layer formed from a non-woven material is secured to sheet 2, again by means of welding around its peripheral margins 12. Sheets 2 and 10 have generally circular openings 14 and 16 respectively through which bodily waste from the stomal orifice of a patient can pass. Welded to sheets 2 and 10 and surrounding the openings 14, 16 is an annular member (hereinafter referred to as the second annular member) 18 formed from a flexible grade of EVA. Second annular member 18 has a semi-circular tab 20, the purpose of which will be apparent from the description below.

Affixed to the second annular member 18 by means of heat sealing is a refastenable adhesive tape 22. The outwardly facing adhesive layer is normally covered with an annular release paper (not shown). The refastenable adhesive tape 22 forms one half of a refastenable tape arrangement of the type available from the Minnesota Mining and Manufacturing Company.

The second annular member is shown in cross-section in Figure 6 and Figure 7 from which it will be noted that surrounding the central opening is a collar portion 24 extending in the direction of the ostomy bag interior. Disposed radially inwardly of the annular collar 24 is a lip seal 26 which extends around the entire inner circumference of the annular collar 24. The lip seal is formed integrally with the second annular member 18.

Referring now to Figures 4 and 5, the adhesive flange 30 is provided with a backing layer coated with hydrocolloid adhesive which serves to adhere the flange to the skin of a patient about the stomal orifice. Adhesive flange 30 has a generally semi-circular tab 32 to assist in removal of the flange after use. Mounted on the adhesive flange by ultrasonic welding is an annular member (hereinafter referred to as the first annular member) 34 which is formed from the same or similar EVA material as the second annular member 18 attached to the ostomy bag. Secured to the first annular member 34 is an annular release layer 36 to which the refastenable adhesive tape 22 on the ostomy bag can be releasably attached.

The first annular member 34 is shown in cross-section in Figures 5 and 7. As can be seen, the first annular member 34 has an upstanding annular rim 38 which in this embodiment extends substantially perpendicularly from the main body 40 of the annular member. The main body 40 of the first annular member 34 has secured to the rear surface thereof a backing layer 42 to which in turn is affixed the hydrocolloid adhesive 44. A release paper 46 covers the hydrocolloid adhesive prior to use. Attached to the front surface of the main body 40 of the first annular member is the release layer 36.

As shown in Figure 4, the first annular member 34 has a pair of guide lugs 48 and 50 located at spaced apart

locations on its peripheral margin.

In use, the patient removes the release paper 46 from the rear surface of the hydrocolloid flange 30, the central hole 52 being cut to the appropriate size to accommodate the protruding end of the stoma. The flange 30 is then adhesively fixed in place about the stomal opening.

The ostomy bag is connected to the adhesive flange by bringing the first annular member 34 and second annular member 18 together so that the collar 24 and lip seal 26 of the second annular member sit about and seal against the upstanding annular rim 38 of the first annular member, thereby providing a substantially water-tight seal between the collar 24 and rim 38. At the same time, the adhesive tape on the second annular member 18 engages the release layer 36 on the first annular member 34 to form an adhesive union between the first and second annular members. In so doing, the ostomy bag is coupled to the adhesive flange.

In time, the ostomy bag will fill up with stomal waste products and will require changing. Rather than remove the entire assembly, the ostomy bag is removed from the adhesive flange by separating the first and second annular members. The semi-circular tabs 20 and 32 can be grasped to assist in the pulling apart of the two annular members. The ostomy bag can then be discarded and a fresh ostomy bag coupled to the adhesive flange.

The advantage of the arrangement illustrated in the drawings is that it is not necessary to tear the adhesive flange away from the patient's skin each time it is necessary to change the ostomy bag. Therefore, much of the irritation and discomfort associated with the fitting and removal of the ostomy bag can be avoided.

The ostomy bag arrangement shown in the drawings is

particularly advantageous in that it is formed from a flexible material and is therefore more comfortable to the patient than existing coupling arrangements formed from more rigid materials. In addition, in many existing two-part coupling arrangements, a mechanical snap-fit fastening arrangement is employed which comprises an upstanding rim on one half of the connector over which a locking ring is snapped. The result is a rather bulky union which is often visible through the patient's clothing. With the present invention, the total height of the two annular members when fitted together is no more than 5mm and can be as little as 3mm. This contrasts with known arrangements in which the two coupling halves are superimposed rather than arranged concentrically and as a result have coupling arrangements 6mm or more in depth.

A further problem with known arrangements is the requirement for accurate positioning of the connector halves, which can present real difficulties for people with impaired manual dexterity. In the present case, the retaining lugs 48 and 50 greatly facilitate the fitting together of the ostomy bag and flange. Thus the ostomy bag can be manipulated until the edge of the second annular member 18 engages one of the lugs 48, 50 and then manipulated further until contact is made with both lugs. At this point, the first and second annular members are correctly positioned and the second annular member 18 can then be fitted over the first annular member 34 as shown in Figure 7.

It will readily be apparent that numerous modifications and alterations can be made to the ostomy bag coupling device shown in the accompanying drawings without departing from the principles underlying the invention and all such modifications and alterations are intended to be embraced by this Application.

CLAIMS

1. A coupling device for mounting an ostomy bag about a stomal opening in the body wall of the patient; the device comprising:

(i) a first annular member having on one side thereof a layer of a dermatologically compatible adhesive for temporarily adhering the first annular member to the patient's skin about the stomal opening, and on the other side thereof having a first annular sealing element, and a first annular bonding region surrounding the first annular sealing element; and

(ii) a second annular member for securing to an ostomy bag about the stomal waste-receiving opening thereof; the second annular member having a second annular sealing element surrounded by a second annular bonding region;

either the first annular bonding region, or the second annular bonding region, or both, having a layer of a repositionable adhesive thereon; the arrangement being such that when the first and second annular members are brought together, the first and second annular sealing elements co-operate to form a substantially water-tight seal, and the first and second annular bonding regions co-operate to form a releasable adhesive bond therebetween.

2. A coupling device according to claim 1 wherein the first and second annular sealing elements are arranged concentrically so that the sealing is effected by radially confronting surfaces of the two sealing elements.

3. A coupling device according to claim 1 or claim 2 wherein one of the first and second annular sealing elements is an upstanding annular rim, and the other

is provided with sealing means for sealing against the upstanding annular ring.

4. A coupling device according to claim 3 wherein the sealing means takes the form of a lip seal.

5. A coupling device according to claim 3 or claim 4 wherein the upstanding annular rim constitutes the first annular sealing element whilst the sealing means (e.g. the lip seal) constitutes the second annular sealing element.

6. A coupling device according to claim 1 wherein one of the annular sealing elements is in the form of an upstanding annular rim, and the other annular sealing element takes the form of an annular collar which fits about the upstanding annular rim, and the depth of the annular collar is such that when the first and second annular members are brought together, the annular collar is substantially flush with the top of the upstanding annular rim.

7. A coupling device according to any one of the preceding claims wherein one of the annular bonding regions has a layer of a releasable adhesive thereon, the releasable adhesive being in the form of an adhesive tape which engages a release tape on the other annular bonding region.

8. A coupling device according to any one of the preceding claims wherein the first and second annular members are formed of a flexible polymeric material.

9. A coupling device according to claim 8 wherein the flexible polymeric material is ethylvinylacetate copolymer (EVA).

10. A coupling device according to claim 8 or claim 9 wherein the first and second annular members are both formed from the same polymeric material.

11. A coupling device according to any one of the preceding claims wherein one or other of the first and second annular members is provided with locating means for assisting correct positioning of one of the annular members with respect to the other.

12. A coupling device according to claim 11 wherein the locating means takes the form of a guide wall or guide lugs attached to one of the annular members, which guide walls or guide lugs are disposed about the periphery of one of the annular members so as to guide the other annular member into a position at which the first and second sealing members can be engaged in sealing contact.

13. A coupling device according to claim 12 wherein the guiding lugs or guiding means are defined by a pair of guide lugs at spaced apart locations on the outer periphery of one of the annular members, and preferably the first annular member.

14. A coupling device according to claim 12 wherein the guide means takes the form of an arcuate guide wall extending between two spaced apart points on the periphery of the annular member.

15. An ostomy bag having a two-part coupling device for mounting the ostomy bag about a stomal opening on the body wall of a patient; the coupling device being as defined in any one of the preceding claims.

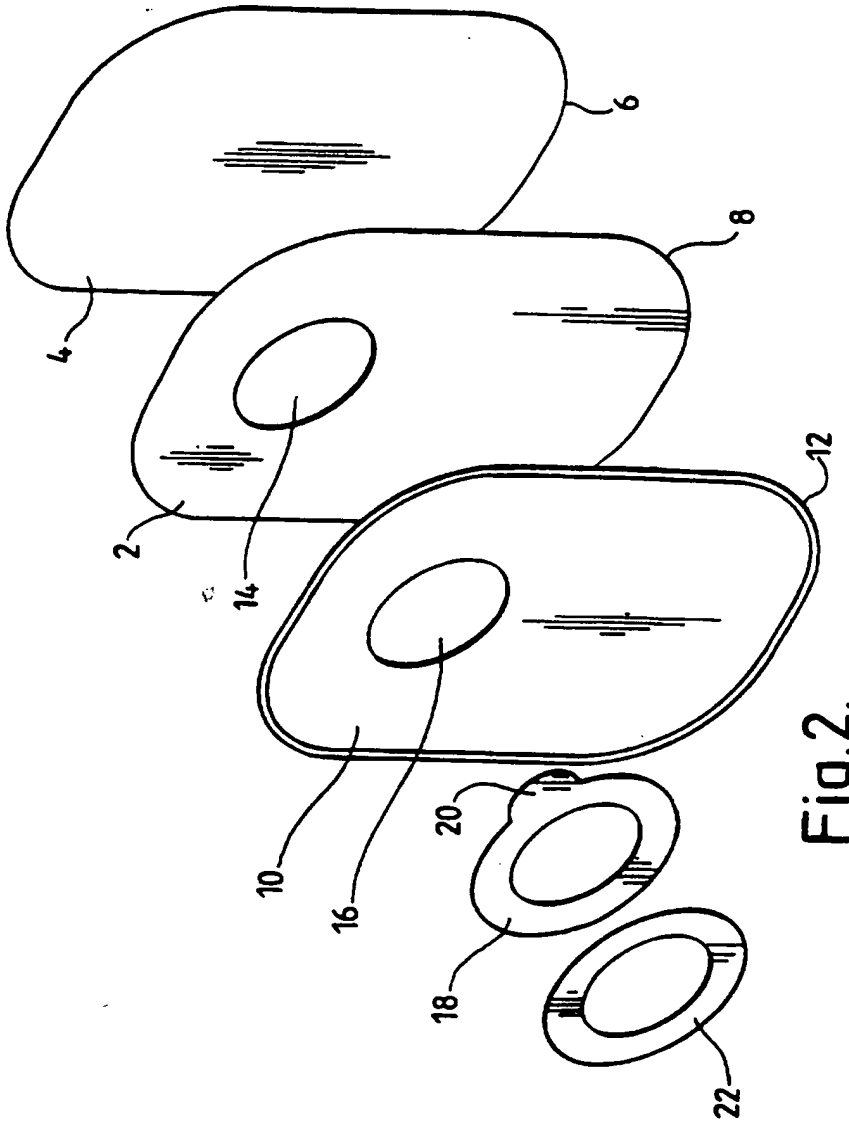

Fig.2.

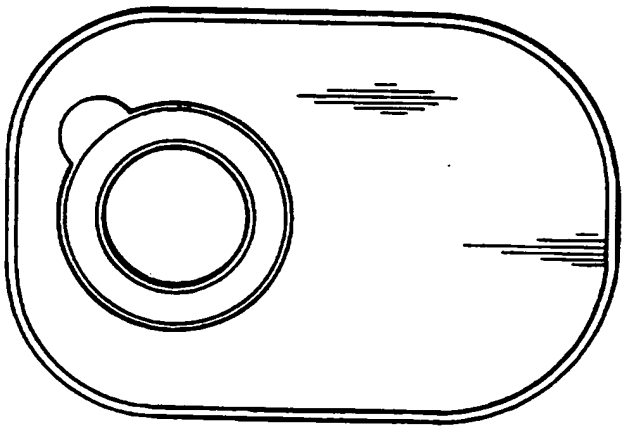

Fig.1.

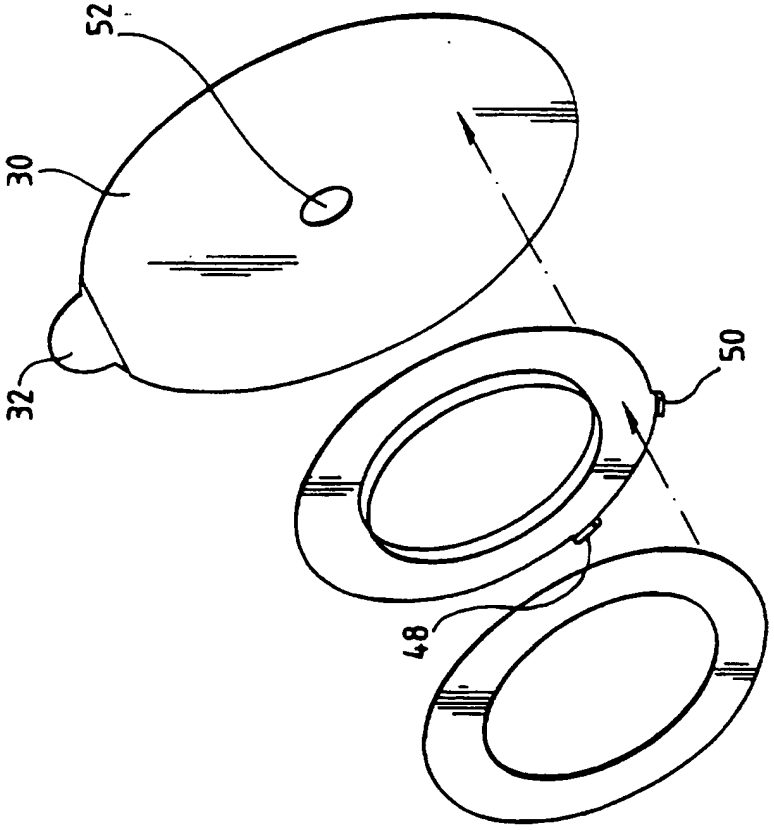

Fig.4.

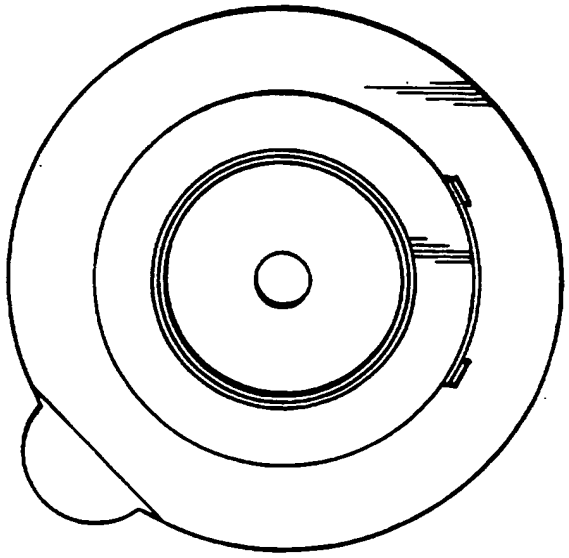

Fig.3.

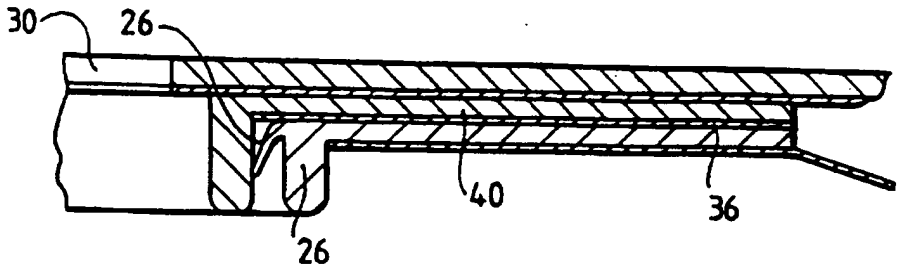

Fig.7.

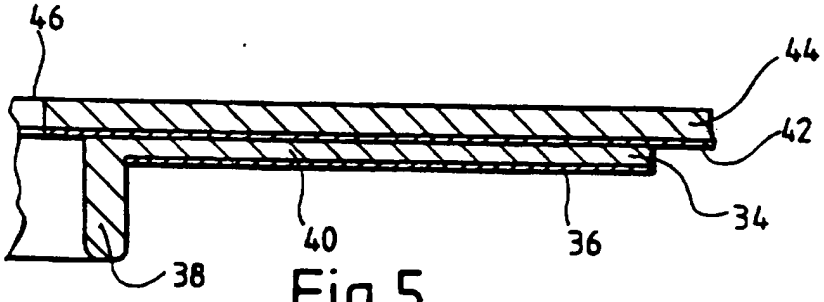

Fig.5.

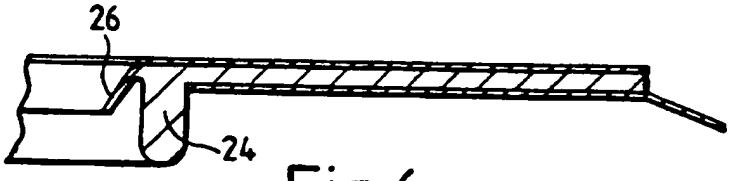

Fig.6.

INTERNATIONAL SEARCH REPORT

Interm al Application No
PCT/GB 97/00815

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F5/443 A61F5/448

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	see page 1, line 61 - line 88; figure 1	6,8,15
A	US 5 346 482 A (METZ MICHAEL ET AL) 13 September 1994	1,7,15
	see column 3, line 33 - line 43; figures	
A	FR 2 638 633 A (SMITHS INDUSTRIES PLC) 11 May 1990	1,7,15
	see page 6, line 17 - line 24; claims 1,8; figures 1,4	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 June 1997	02.07.97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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